K103832

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

MAY 2 0 2011

Special 510(k)
Phoenix® System 3.40



## 510(k) SUMMARY

| | |
|---|---|
| **Submitter's Name** | Gambro Renal Products, Inc |
| **Address** | 14143 Denver West Parkway, Suite 400<br>Lakewood, Colorado 80401 |
| **Establishment Registration Number** | 2087532 |
| **Contact Person** | Kae Miller, Regulatory Affairs Manager |
| **Telephone Number** | (303) 222.6724 |
| **Fax Number** | (303) 222.6914 |
| **Date of Summary** | December 27, 2010 |

| **Subject Device** | |
|---|---|
| **Name of the Device** | Phoenix® Hemodialysis Delivery System – version 3.40 |
| **Catalogue Number** | 6023006700 |
| **Common or Usual Name** | Hemodialysis Delivery System |
| **Classification Name** | High Permeability Hemodialysis System |
| **Device Class** | II |
| **Product Code** | 78KDI |
| **Regulation Number** | 876.5860 |

| **Legally Marketed Device (Predicate Device)** | |
|---|---|
| **Name of the Device** | Phoenix® Hemodialysis Delivery System – version 3.35 |
| **Catalogue Number** | 6023006700 |
| **Common or Usual Name** | Hemodialysis Delivery System |
| **Classification Name** | High Permeability Hemodialysis System |
| **Device Class** | II |
| **Product Code** | 78KDI |
| **Regulation Number** | 876.5860 |
| **510(k) number** | K070643 |

**510(k) SUMMARY, continued**

**Device Description**

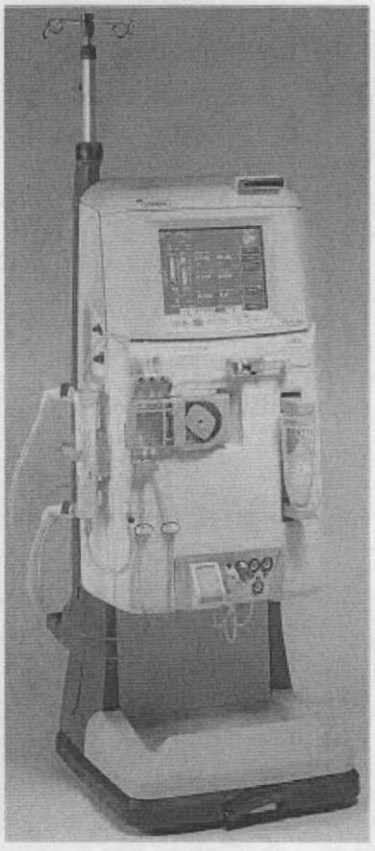

**FIGURE 1: Phoenix Hemodialysis Machine**

Phoenix is a self-contained, microprocessor-controlled device that provides hemodialysis, hemofiltration and ultrafiltration therapies. The system consists of the Hemodialysis Machine in use with a blood tubing set designed for the machine, a dialyzer, a heparin-filled syringe, a BiCart® column (sodium bicarbonate powder), and other appropriate dialysate concentrates.
The machine has many built-in features which are intended to enhance the ease of providing patient dialysis treatments.

The Phoenix Hemodialysis Machine pumps blood from the patient, in a blood tubing set properly designed for the machine, through the dialyzer where purification takes place, and back to the patient.

In the dialyzer, the blood and the dialysate fluid flow on opposite surfaces of a thin Semipermeable membrane. As the blood passes through the filter, the desired treatment processes take place. Depending upon the therapy in use, the treatment processes can include fluid removal and/or solute clearance.

Phoenix has a modular structure. It is made up of five modules that carry out independent functions: Master Module, Hydraulic Module, Blood Module, Protection Module and Bio Module. The unit consisting of the Master, Hydraulic and Blood Modules is called the Control System. The Control System manages the implementation of the physical functions.

The Phoenix machine can carry out the following therapies:

- **Ultrafiltration**; the body's excess fluid is removed through the dialyzer membrane by means of a pressure gradient between the blood and dialysate compartments in the dialyzer.
- **Hemofiltration**; accumulated metabolic products are removed from blood by the process of convective transport as a consequence of ultrafiltration of fluid across a dialyzer semi-permeable membrane of high-flux type. The volume of filtered fluid that exceeds the desired weight loss is replaced by sterile pyrogen-free infusion solution infused into the blood flowpath.
- **Hemodialysis**; the chemical composition of blood is corrected by removing accumulated metabolic products, normalizing ionic content and adding buffer through the process of diffusive transport.

**510(k) SUMMARY, continued**

**Physical Characteristics**

| Parameter | Dimension |
|---|---|
| Height | 1440 mm (56.7 in) |
| | 1970 mm (77.4 in) with "IV Pole" |
| Width | 610 mm (24.0 in) with "Dialyzer holder" in working position |
| Depth of base | 710 mm (27.9 in) |
| | 930 mm (36.5 in) with "Chemical Container Shelf" |
| Total floor surface covered by base | 433100 mm² (671.3 in²) |
| | 567300 mm² (879.3 in²) |
| Dry weight | 120 kg (264.5 lb) |

**Indications For Use of the predicate device: Phoenix version 3.35**
The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.

**Indications For Use of the subject device: Phoenix version 3.40**
The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.

**Note:**
The Indications For Use of the proposed device and of the predicate device are identical. There is no change of the indications for use, intended use of hemodialysis system, or affect on the fundamental scientific technology. Due to the physical characteristics of the low weight – low volume set, the user must currently divide the following displayed parameter values by 4 to determine the actual parameter values: blood flow, liters processed, and pump speed. With the 3.40 version of the software, there is no need to perform any mathematical calculations; all displayed values are the actual for the low weight – low volume set.

**510(k) SUMMARY, continued**

**Device Comparison Table**

In the following table the proposed device Phoenix® Hemodialysis Delivery System – version 3.40 is compared with the predicate device Phoenix® Hemodialysis Delivery System – version 3.35 (K070643).

| | Subject device – Phoenix sw 3.40 | Predicate device – Phoenix sw 3.35 |
|---|---|---|
| **Indications for Use** | The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit. | The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit. |
| **Dedicated Disposable Sets** | Gambro Cartridge™ Blood Set:<br>003410-510 Double Needle<br>003410-710 Double Needle<br>003414-500 Double Needle<br>003414-510 Double Needle<br><br>003409-410 Single Needle<br>003429-500 Single Needle<br>Conversion Kit<br><br>003412-500 Double Needle<br>(75 ml VOLUME)<br><br>003422-520 Double Needle<br>(LOW WEIGHT – LOW VOLUME) | Gambro Cartridge™ Blood Set:<br>003410-510 Double Needle<br>003410-710 Double Needle<br>003414-500 Double Needle<br>003414-510 Double Needle<br><br>003409-410 Single Needle<br>003429-500 Single Needle<br>Conversion Kit<br><br>003412-500 Double Needle<br>(20-40 Kg weight) |
| **Anticoagulation** | Heparin Syringe Pump<br>0/0.5 – 9.9 ml/hr<br><br>Accuracy:<br>± 5% or ± 0.2 ml/h | Heparin Syringe Pump<br>0/0.5 – 9.9* ml/hr<br><br>Accuracy:<br>± 5% or ± 0.2 ml/h |
| **Blood Flow Rate** | 10 – 580 ml/min<br>(10 – 140 ml/min in LW-LV mode)<br>Accuracy ± 10% if pressure before the pump is not lower (more negative) than – 150 mmHg | 10 – 580 ml/min<br><br>Accuracy ± 10% if pressure before the pump is not lower (more negative) than – 150 mmHg |

*Note: submission (K070643) noted this as 10 ml/hr in summary, but actual value without rounding is 9.9 as reflected in Operator's Manual. This value has not changed between software versions.

**510(k) SUMMARY, continued**

| | Proposed device – Phoenix sw 3.40 | Predicate device – Phoenix sw 3.35 |
|---|---|---|
| **Fluid Removal Rate from Patient** | 0 – 4 Kg/h<br>Dialysate flow rate at 350 ml/min:<br>Accuracy (on total Weight removed):<br>±(2% UF rate + 35 g/hr)<br>Dialysate flow rate at 500 ml/min:<br>Accuracy (on total Weight removed):<br>±(2% UF rate + 50 g/hr)<br>Dialysate flow rate at 800 ml/min:<br>Accuracy (on total Weight removed):<br>±(2% UF rate + 80 g/hr) | 0 – 4 Kg/h<br>Dialysate flow rate at 350 ml/min:<br>Accuracy (on total Weight removed):<br>±(2% UF rate + 35 g/hr)<br>Dialysate flow rate at 500 ml/min:<br>Accuracy (on total Weight removed):<br>±(2% UF rate + 50 g/hr)<br>Dialysate flow rate at 800 ml/min:<br>Accuracy (on total Weight removed):<br>±(2% UF rate + 80 g/hr) |
| **Dialysate Flow Rate** | 350 – 800 ml/min<br>Accuracy: ± 5% | 350 – 800 ml/min<br>Accuracy: ± 5% |
| **Transmembrane Pressure** | -100 to +450 mmHg | -100 to +450 mmHg |
| **Ultrafiltration Rate** | 0 – 4 Kg/h<br>Accuracy:<br>±2 % of actual value | 0 – 4 Kg/h<br>Accuracy:<br>±2 % of actual value |
| **Dialysate Temperature** | 34 – 39.5 °C | 34 – 39.5 °C |
| **Dialysate Conductivity** | 13-17 mS/cm | 13-17 mS/cm |
| **Arterial and Venous Pressure** | Arterial: -400 to +150 mmHg<br>Venous: 0 to +450 mmHg | Arterial: -400 to +150 mmHg<br>Venous: 0 to +450 mmHg |

**Non-clinical performance data**

The non-clinical testing for this new software version allowed to determine the substantial equivalence with the predicate device and consisted of verification and validation activities for the software and the system, with static tasks (impact analysis, final phase reviews, code inspections, system and software test protocols preparation) and dynamic tasks (baseline verification, system and software test protocols execution, regression testing, Graphical User Interface and Use Cases test execution), verification and validation of the labeling, Usability validation (formative and summative), risk management activities, and compliance with applicable international safety standards for dialysis equipment.

**Clinical performance data**

No clinical studies were performed for the software modification.

**510(k) SUMMARY, continued**

**Conclusion of Safety and Effectiveness**

The successful completion of the following verification and validation activities:

- Static activities code reviews;
- System and software functional tests;
- Labeling evaluations as part of usability testing;
- Standards compliance to IEC standards 60601-1, 60601-1-2, 60601-2-16, 60601-1-4, 60601-1-6, 62366; and
- Usability validation,

demonstrates the safety and effectiveness of the Gambro Phoenix® Hemodialysis Delivery System – version 3.40 when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Kae Miller
Regulatory Affairs Manager
Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
LAKEWOOD CO 80401

MAY 20 2011

Re: K103832
Trade/Device Name: Phoenix® Hemodialysis Delivery System – version 3.40
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 19, 2011
Received: April 21, 2011

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401



**Indications for Use**

510(k) Number (if known): K103832

Device Name: Phoenix® Hemodialysis Delivery System – version 3.40

Indications for Use:

The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103832